EXHIBIT O

Gynecare

TVT™ Obturator System

Tension-free Support for Incontinence

GYNECARE TVT™ obturatorsystem
Spændingsfri støtte til inkontinens

GYNECARE TVT™ obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT™ -obturaattorijärjestelmä
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT™
Dispositif sans tension contre les incontinences

GYNECARE TVT™ Obturatorsystem
Spannungsfreie Unterstützung bei Inkontinenz

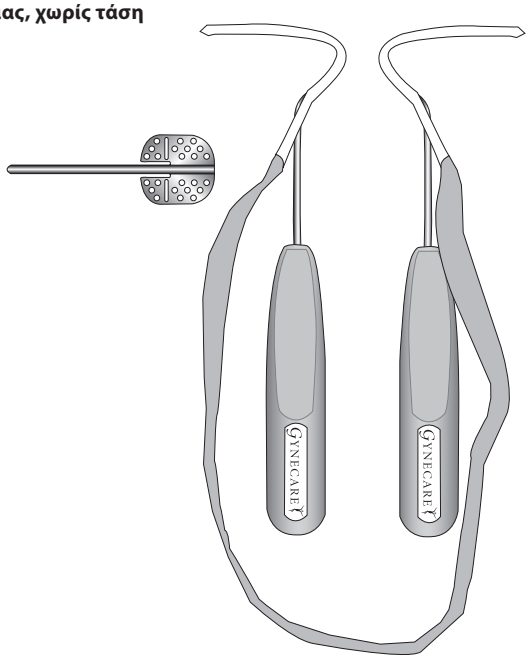
Sistema otturatorio GYNECARE TVT™
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT™
Suporte sem tensão para incontinência

Sistema obturador GYNECARE TVT™
Protector sin tensión para la incontinencia

GYNECARE TVT™ obturatoriabandsystem
Spänningsfritt inkontinensstöd

Σύστημα επιπωματικού GYNECARE TVT™
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



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LAB0010875v5
01/2015
Made in Switzerland

Ethicon, SÀRL
Puits Godet 20
Neuchâtel
CH-2000
Switzerland
1-877-ETHICON
+1-513-337-6928

ENGLISH

GYNECARE TVT™ Obturator System
Tension-free Support for Incontinence

GYNECARE TVT Obturator Device, Sterile Single Use

GYNECARE TVT Obturator Helical Passers, Sterile Single Use

GYNECARE TVT Obturator Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT™ Obturator System, including the GYNECARE TVT Obturator device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT™ Obturator System is a sterile, single patient use procedure kit available in either mechanical cut or laser cut versions for the physician's preference. To determine if the GYNECARE TVT™ Obturator System implant is mechanical or laser cut, consult the product code on the device packaging; an (L) at the end of the number indicates the laser cut mesh.

The GYNECARE TVT Obturator System consists of:

GYNECARE TVT Obturator device

The GYNECARE TVT Obturator device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Color index Number 74160) PROLENE™ polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE Mesh is knitted by a process that interlinks each fiber junction and that provides elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT Obturator device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

PATIENT FACTORS

Physicians should use their surgical experience and judgment to determine if PROLENE Mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. If desired, retract the labia to provide additional exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.

5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

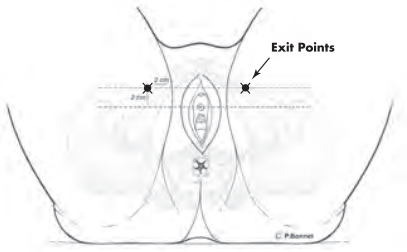

FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

   (Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

   After initiating sharp dissection, continue by using a "push-spread technique", to perform blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented on the horizontal plane. *(See Figure 2)* Continue dissection towards the junction between the body of the pubic bones and the inferior pubic ramus. *(See Figure 2)*

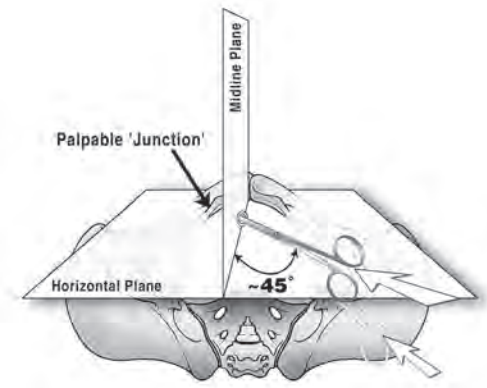

FIG. 2

When the junction between the body of the pubic bones and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the internal package workstation from the external package. Then remove the GYNECARE TVT Winged Guide from the package workstation. *(See Figure 3)*

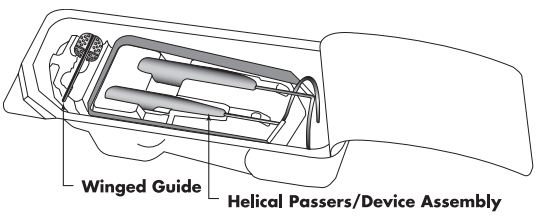

FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

   If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

   (Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack *(See Figure 3 for components).*

   (Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

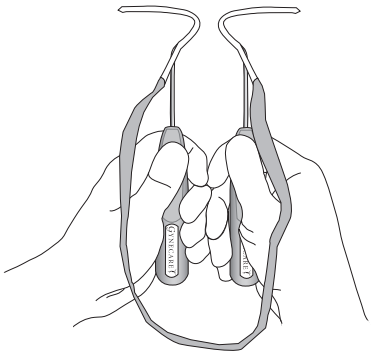

FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.

11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. *(See Figure 5)*

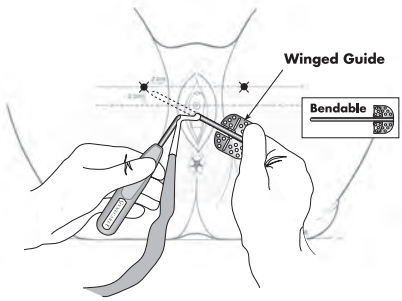

FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

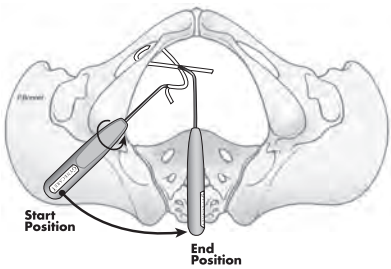

FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer as you simultaneously move towards the midline until the handle is vertical to the floor. *(See Figure 6)*

    (Note: Never allow the handle to be oriented horizontal to the floor.)

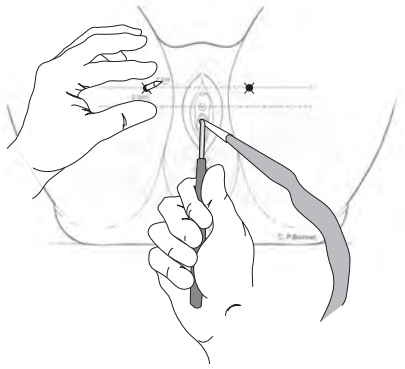

FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points. *(See Figure 7)* However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the Helical Passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp the pointed tip of the plastic tube with a clamp and, while stabilizing the tube near the urethra with the thumb, remove the Helical Passer by a reverse rotation of the handle. *(See Figure 8)*

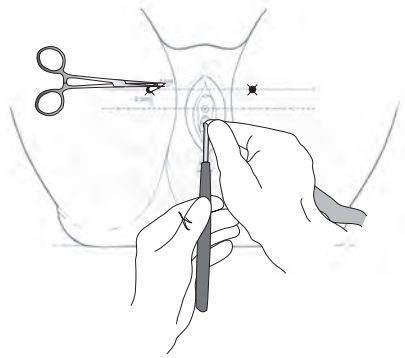

FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. *(See Figure 9)*

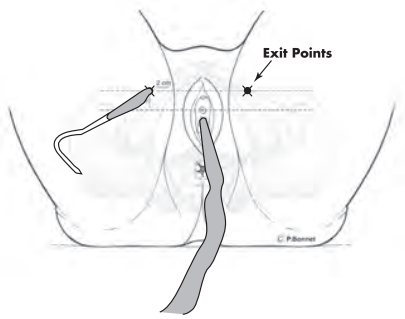

FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. *(See Figure 10)*

    (Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

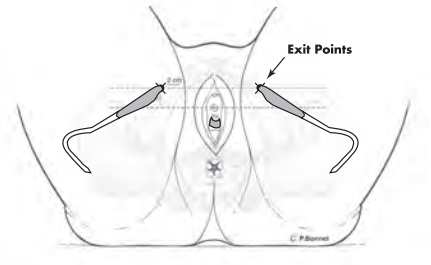

FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the midurethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. *(See Figure 11)*

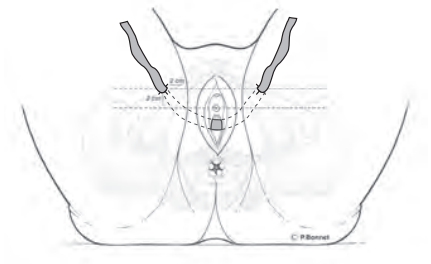

FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. Place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths, or use other suitable means during sheath removal, to avoid positioning the tape with tension.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.

19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT Obturator in patients who are on anti-coagulation therapy. Do not use GYNECARE TVT Obturator in a patient who has a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator device.
- Acceptable surgical practice should be followed for the procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Obturator System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT Obturator System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System. To minimize this risk, make sure to place the tape as described above. Do not contact the PROLENE Mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- The plastic sheaths initially covering the PROLENE Mesh are designed to minimize the risk of contamination. Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

ACTIONS

Animal studies show that implantation of PROLENE Mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

The GYNECARE TVT Obturator System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Store at or below 25°C. Do not use after expiration date.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

SYMBOLS USED ON LABELING

	Caution		Upper limit of temperature
	Do not reuse	REF	Catalogue number
	Do not resterilize	STERILE EO	Sterilized using Ethylene Oxide
	Do not use if package is damaged		Manufacturer
	Use by–year and month	LOT	Batch code
Rx only	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.	CE 0086	CE mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC